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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,333	08/20/2003	Bernd Disse	1/1196-1-C1	6665

28519 7590 04/30/2007
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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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04/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,333

Applicant(s)

DISSE, BERND

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/096810.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/8/2007 has been entered.

Status of Application

1. Acknowledgement is made of amendment filed 2/8/07 . Upon entering the amendment, the claims 9, 11, 13 are amended and the claim 10 is canceled. New claims 14-32 are added.
2. The claims 9, 11-32 are pending and presented for the examination.

Response to Arguments

1. Applicant's arguments with respect to claims pending have been considered but are moot in view of the new ground(s) of rejection due to the scope changes made into instant claims now amended.

Claim Rejections - 35 USC § 112,2nd

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claim 9 recites the limitation "**the** inflammatory component" in line 1. Claim 11 also recites the limitation "**the** anion of" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 9, 11-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Pairet et al(US 2002/0122773).

The claims are drawn to a method for treating the inflammatory component of a disease such as cystic fibrosis using an effective amount of a tiotropium salt(e.g. bromide or methanesulphonate) via inhalation.

Pairet et al(US'773, hereafter) teaches a treatment of respiratory tract diseases using tiotropium compound containing composition, see abstract. Especially, the teaching of US'773 relates to a inhaler(i.e. nebulizer) containing tiotropium salt(e.g. as counter-ion(anion) such as bromide or methanesulphonate, see paragraph 11).

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Furthermore, the composition of US'773 is effectively treating an inflammatory diseases of respiratory tract including cystic fibrosis, see paragraph 30 at page 2.

As to claims 14 and 16-18, US'773 teaches inhalable powders and aerosols using propellant gas such as HFA134a, HFA227, TG134a, or TG227, see paragraphs 26 and 49.

As to claims 15 and 20-30, US'773 teaches excipients such as polyalcohols or polysaccharides at paragraph 42; other ingredients such as co-solvents, stabilizers, pH adjusters at paragraph 50; alcohol and glycol as co-solvents(paragraph at 57; pH of 2-7 at paragraph 55; and vitamins at paragraph 58, editic acid , sodium editate and benzakonium chloride at paragraphs 56 and 60; and so on.

All the critical elements are well taught by the cited reference and all the claimed subject matter is clearly anticipated over the prior art of the record.

Conclusion

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'VICKIE KIM', with a long, sweeping horizontal line extending to the right.

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
April 26, 2007
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